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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,048	12/09/2003	Masahide Hoshino	242342US0DIV	2993
22850	7590	11/30/2007		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER * YU, GINA C	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 11/30/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
oblonpat@oblon.com  
jgardner@oblon.com

**Office Action Summary**

Application No.

10/730,048

Applicant(s)

HOSHINO ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7,9 and 15-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7,9 and 15-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of amendment filed on August 31, 2007. Claims 7, 9, 15-31 are pending. Claim rejections made under 35 U.S.C. § 112, first and second paragraphs as indicated in the previous Office action dated June 4, 2007, are withdrawn in view of the claim amendment made by applicants. Obviousness double patenting rejection is withdrawn in view of applicants' remarks.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "reinforcing the water retaining ability of the horny layer or a skin barrier function" and "remedying skin roughness", does not reasonably provide enablement for "***preventing*** skin roughness". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to using the invention commensurate in scope with these claims.

Evaluating enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: a) the breadth of the claims; b) the nature of the invention; c) the state of the prior art, the level of one of ordinary skill; d) the level of predictability in the art; e) the amount of direction provided by the

inventor; f) the existence of working examples; and g) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

a) the breath of the claims: The scope of the claim encompasses method of reinforcing the water retaining ability of the horny layer or a skin barrier function and preventing or remedying skin roughness by applying to the skin a diamide composition.

b) the nature of the invention: The nature of the invention is a skin treatment method to improve skin barrier function and skin roughness by topically applying a composition comprising an effective amount of a specific class of diamide.

c) the state of the prior art: the prior art indicate that diamides are used to improve the barrier function of the stratum corneum, dermatitis, skin roughness, or similar disorders. See US 5753707, abstract. Although the reference states in the specification that the prior art diamide prevents skin roughness, there is no working examples or disclosure that enables a skilled artisan to prevent the symptom.

d) the level of predictability in the art: It is highly unpredictable that topical treatment with a diamide is capable of total prevention of skin roughness because the condition may be caused by factors that are not necessarily associated with the water retaining ability of the skin or skin barrier function. For example, rough skin is caused by photoaging, chemical irritation, water, surfactants and solvents that are regularly contacted on the skin. See Poucher's Perfumes, Cosmetics and Soaps, 405, 407-8, 686.

e) the amount of direction provided by the inventor: There is no direction in the specification as to how to use the compound in treating the skin other than to improve water retention property and barrier function of the skin.

f) the existence of working examples: There is no working example in the specification as to how to use the compound for total prevention of skin roughness.

The burden of enabling the prevention of a skin condition (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such conditions, which may be caused by various factors, particularly by extrinsic factors that the patients commonly encounter. Furthermore, the specification does not provide guidance as to how one skilled in the art would go about preventing those patients susceptible to skin roughness within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing the skin conditions among the patients. The specification fails to enable "prevention", and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method for the prevention of rough skin.

***Allowable Subject Matter***

Claims 9, 23-31 are allowed.

Claim 7 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 1<sup>st</sup> paragraph, set forth in this Office action.

Claims 15-22 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1<sup>st</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments with respect to claims 7, 9, 15-31 have been considered but are moot in view of the new ground(s) of rejection in part as stated above, and persuasive in part.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

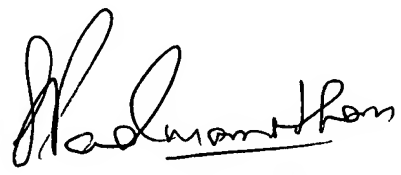
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina C. Yu  
Patent Examiner



SREENI PADMANABHAN  
SUPERVISOR, PATENT EXAMINER